
Food and Drug Administration
Rockville MD 20857

NDA 20-286/S-004

Bristol-Myers Squibb
Attention: Ms. Grace Heckman
P. O. Box 4000
Princeton, NJ 08543-4000

Dear Ms. Heckman:

Please refer to your supplemental new drug application dated August 25, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monopril HCT (fosinopril sodium/hydrochlorothiazide) 10/12.5 and 20/12.5 mg Tablets.

We acknowledge receipt of your submissions dated April 7, 2000 and January 18, 2001. Your submission of January 18, 2001 constituted a complete response to our April 4, 2000 action letter.

This supplemental new drug application provides for final printed labeling revised as follows:

- 1) To include a **PRECAUTIONS/Geriatric Use** subsection:

Clinical studies of fosinopril sodium/hydrochlorothiazide did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

- 2) To change the Storage subsection from:

Store at 15°-30° C (59°-86°); avoid prolonged exposures to temperatures above this range.

to:

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86° F) [see USP Controlled Room temperature].

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your January 18, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Sandra Birdsong
Regulatory Health Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
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